UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,570	10/24/2003	Shigeru Nemoto	244406US2	6947

22850 7590 04/04/2012

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
CWERN, JONATHAN	

ART UNIT	PAPER NUMBER
3737	

NOTIFICATION DATE	DELIVERY MODE
04/04/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/691,570	NEMOTO, SHIGERU	
	Examiner	Art Unit	
	JONATHAN CWERN	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *40,41 and 45-49* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *40,41 and 45-49* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/16/11 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-41 and 45-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 40, it is unclear where there is support in the specification for the claim limitation: "the injection rate of the base-operation condition is configured to be changed based on the volume of said contrast medium".

Also, in claim 40, it is unclear where there is support in the specification for the claim limitation: "said injection control means is configured to read out, from a condition storage device, a base-operation condition including data of: ...a waveform of an injection rate." While applicant indicates that Figure 10 is a drawing of the waveform, it is unclear where it is recited that the control means reads out this waveform to use as data of the base operating condition. It seems that Figure 10 may just be provided as a visual aid for observing the variable injection pattern, and may not be used as actual data which is input into the system.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-41 and 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 41, in step (iv) to perform the injection, "the calculated injection pattern" lacks antecedent basis. The language in step (iii) was changed from "calculating an injection pattern" to "make".

In claim 41, in the last paragraph, the phrase "based on the volume of said contrast medium" is unclear if it refers to "the calculated necessary volume of contrast medium" or some other measurement of the volume of the contrast medium.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40-41 and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al. (US 5840026) in view of Duchon et al. (US 2003/0018252), Cherek et al. (US 2004/0081341), and Dahlin et al. (US 2004/0078215).

Uber et al. disclose a patient specific dosing contrast delivery system. The system first allows for a user to enter patient specific data such as the patient's size and weight. This data can also be downloaded from an external database. The system then determines the appropriate concentration of the contrast media, as well as the appropriate flow rate, volume, time delay, etc. The system also takes into account imaging parameters such as the section of the body being imaged, and can automatically adjust based on a desired image quality or sensed amount of contrast media (volume) in the body. The concentration of contrast agent can also be adjusted by adding in a diluent (column 5, line 20-column 6, line 52; column 8, lines 1-7; column 12, lines 5-26). Based on the sensed data, the injection parameters may be adjusted. Thus, the injection rate may be adjusted without changing the predetermined injection time (column 10, lines 1-15; column 11, lines 60-67). In general, the system allows for control over many typical imaging and contrast delivery parameters, and allows for both

automated delivery using predetermined values and also a wide range of user customization if desired. Table 1 (column 8) shows a number of parameters, including length of scanning and duration of injection. Thus these parameters may be predetermined or selected by the user. Thus, by using a predetermined length of scanning or duration of the injection, the system would adjust other values (such as flow rate or injection rate) based on the patient's specific data (such as size or weight) in order to achieve the desired scan time or duration of the injection. Furthermore, Uber et al. note that in comparison to the prior art, the system of Uber et al. is able to adjust the flow rate, concentration, and or stop the injection sooner than originally planned. This further indicates that there is a planned (predetermined) time period for the injection. Different doctors may also have different desired preferences for these parameters (column 13, lines 30-50), illustrating the amount of customization the system allows for. Thus each doctor may have a different desired length of scanning or duration of the injection which they wish to use, and the system can load this data and adjust other parameters such as injection rate to achieve these goals taking into account the patient's specific data such as size or weight. Thus a user can select (or the system can automatically load) the predetermined injection time to be unchanged and the system will adjust the injection rate based on the user's weight. It would be obvious to one of ordinary skill in the art to customize any of these parameters depending on the specific patient being diagnosed and the user's preferences. Uber et al. fail to show a touch screen user interface.

Duchon et al. disclose an angiographic injector system. Duchon et al. teach a touch screen that is used to select injection parameters ([0022]). Duchon et al. also teach injecting saline ([0074]).

Cherek et al. disclose a method for positioning a patient. Cherek et al. teach a touch screen which displays a patient's body, and scans an area of the patient's body based on which area of the body is selected ([0010]).

Dahlin et al. disclose a system for documenting medical findings. Dahlin et al. teach a touch screen user interface which can display a region of the body, and when an area is selected, can further zoom in to display that area of the body in more detail ([0086]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the system of Uber et al. to use a touch screen as taught by Duchon et al., as this will provide the user with a simple control over the operation of the system. A variety of different user interfaces could be provided on the touch screen for controlling various portions of the operation, as is well known in the art. Cherek et al. and Dahlin et al. provide specific examples of such user interfaces which could be employed in the combined system of Uber et al. and Duchon et al. Providing an image of the body for the user to select the desired area being imaged will provide a simple and intuitive way for the user to select the desired area.

Response to Arguments

Applicant's arguments filed 11/16/11 have been fully considered but they are not persuasive.

In regards to applicant's argument that the duration of the injection is not a determined parameter, examiner respectfully disagrees. The duration of the injection is variable, in the sense that different patients (or the same patient at different times) may require different durations. However, for a given patient, the duration of the injection is one parameter which is calculated by the system. Indeed, the very purpose of determining a desired concentration level, and a rate of flow (concentration delivered per unit time), is to deliver the contrast agent over a specific amount of time to reach the desired concentration level. The very purpose of adjusting a rate of flow, is to adjust how quickly or how slowly the contrast agent is delivered into the patient over a given period of time. Thus, for example, if the sensor determines that the concentration is lower than expected at a given time in the procedure, the rate of flow may be increased. Furthermore, the only time the predetermined injection time is described as changing in Uber et al., is if the system experiences some serious problem, the system may automatically stop the injection procedure, thus shortening the injection time (column 10, lines 9-15). Uber et al. also hint at a predetermined injection time in column 10, lines 40-48, when describing that the injection may be stopped "sooner than originally planned". That is, there is a "planned" (predetermined) injection time. Furthermore, the fact that the "duration of injection" is a variable indicates that it is a value that may be changed or unchanged.

In regards to applicant's arguments that Uber et al. do not include determining the injection time, particularly for a selected region, examiner respectfully disagrees. The region to be imaged is a critical feature, in order to be able to accurately determine the appropriate amount of contrast agent, as this will vary widely based on the region of the body to be imaged, as is well known in the art. The "procedure/body location" is an input parameter in Table I, and furthermore is specifically described in column 6, lines 20-30; the section of the body to be imaged.

In regards to applicant's arguments that the flow rate constantly being adjusted leads to different and undetermined injection times, examiner respectfully disagrees. As described in the example above, the flow rate may be adjusted without changing the predetermined injection time. Indeed, the opposite is true. If one wanted to change the predetermined injection time, they could leave the flow rate unchanged. That is, increasing the flow rate increases how much contrast agent is injected per unit time, so that the overall injection time may remain unchanged.

Furthermore, the examiner is unable to offer any guidance on how the claims may be amended to place them in condition for allowance. Applicant's specification for example states that the object of the present invention is to provide a liquid injector which allows the operator to inject a contrast medium into a subject through a simple operating process. Applicant describes in the background section that prior art injectors are disadvantaged in that the operator is required to perform the calculations and manually enter the values, and that this must be done separately for the contrast medium and saline. A solution for this problem has already been provided for in the

prior art, in the automated system of Uber et al., and thus the examiner fails to see what the intended novelty of applicant's currently claimed invention is. Perhaps an explanation of what problem in the prior art the currently claimed invention seeks to solve would aid in helping the examiner to understand applicant's intention and aid in advancing prosecution.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN CWERN whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737